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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MADUZN

Refer to: CFN 1120934

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040
Fax: (410) 962-2219

November 19, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James S. Cladius, President
Weirton Wholesale Distribution Co., Inc.
3550 Rear Main Street
Weirton, West Virginia 26062

Dear Mr. Cladius:

During an inspection of your multiple foods warehouse conducted by the Food and Drug Administration on November 3 - 4, 1998, our investigators documented deviations from the Good Manufacturing Practices (GMP) Regulations, (Title 21, Code of Federal Regulations, Part 110) with respect to your firm's holding of various packaged food products. These deviations from GMPs cause your products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that the products have been held under insanitary conditions whereby they may have become contaminated with filth.

Our inspection found the presence of an active rodent infestation within and throughout the food storage area of your warehouse and building defects suitable for rodent entry. The inspection revealed rodent defiled products such as Mrs. Grass Soup Mix and Borte Chocolate Balls. Evidence of rodent activity associated with these articles included gnawed product containers, rodent excreta, and fluorescing stain indicative of rodent urine.

Additional rodent activity observed by our investigators included: 1) over 150 rodent excreta pellets in multiple locations throughout the warehouse in close proximity to stored food items and single service food containers; 2) apparent rodent gnawed Styrofoam single service food containers; 3) apparent rodent tracks on canned goods.

Our investigators also observed a large accumulation of refuse stored along the outside of the east wall of the building. This observation was not listed on the FDA-483 issued to you at the close of the inspection, however we feel it is important that you eliminate any potential rodent harborage from your premises.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627 at extension 14.

Sincerely,

Carl E. Draper
Acting Director, Baltimore District

cc: West Virginia Department of Agriculture
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305